

REMARKS

Claims 49-55, 57-66 and 69-73 were under examination as of the issuance of the Office Action of November 2, 2006. By the current Amendment to Claims, claims 50, 51 and 71-73 have been amended and claim 55 has been cancelled without prejudice.

Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed. Specifically, support for the amendment to claims 50 and 51 can be found throughout the specification, for example, at page 32, line 16 to page 33, line 25, and in the claims as originally filed, for example, claims 67-68.

Applicants respectfully request that the aforementioned amendments be entered. No new matter has been added by the foregoing amendments to the claims. Applicants note that the foregoing amendments and cancellation of a claim have been made solely in order to expedite examination and in no way should be construed as an acquiescence to the validity of the rejections set forth in the Office Action. Following entry of the foregoing amendments, claims 49-54, 57-66 and 69-73 will remain pending in the present application.

Priority

The Office Action sets forth that claims 49-51 as previously presented do not find support in the specification as originally filed on the grounds that

the claims as amended (49-51 and dependent claims) recite a particular subgenus that is not supported by the original application... Page 33 lines 22-25 recite a condition for X_9 , but do not recite the subgenus of the current claims. For example, page 33 lines 10 and 13 support a peptide in which R is replaced and X_6 is replaced. However, claims 49-50 support a subgenus in which R can be unchanged (i.e. does not agree with original disclosure of R is replaced). Claims 49-51 support a subgenus in which X_6 can be unchanged (i.e. does not agree with original disclosure of X_6 is replaced). Although applicants claim support from claims 67-68 as originally filed, there were no claims 67-68 as originally filed. Hence, claims 49-55, 57-66 [and] 69-70 do not receive the priority date of the originally filed application.

Applicants respectfully disagree. Applicants submit that the present application as originally filed, in addition to the originally filed specification of priority U.S. Application No. 10/441952, filed May 19, 2003, the teachings of which are incorporated by reference into the present application, each provide sufficient support for the claimed peptides.

Applicants respectfully submit that the Examiner's characterization of the specification in the Office Action is incorrect. Applicants submit that the Examiner's characterization of the teachings of the specification, specifically, the embodiments of the invention as set forth on page 33, lines 8-25 and on page 34, line 19 to page 35, line 5 of the present specification (and on page 36, line 6 to page 39, line 13 of priority U.S. Application No. 10/441952) is improper.

Applicants submit that while the Examiner has interpreted, for example, the teachings of page 33, lines 8-25, as requiring that the peptides of the invention have each of the features set forth in items (a) – (e), such interpretation is contrary to the teachings of the specification, as would be understood by one skilled in the art. Indeed, Applicants submit that the teachings of the specification ***do not, in fact, require that the disclosed embodiment comply with each of the features set forth in items (a) – (e).*** Instead, the specification provides such features as exemplary.

Applicants submit that the context of the teachings of the specification confirms such interpretation of the present specification. In support, Applicants direct the Examiner's attention to the specific pentapeptides listed in the application, see, for example, page 35, line 11 through page 39, in which certain embodiments include ***only one or more residues R, X₆ X₇ X₈ and X₉ that fall within the categories of one or more of items (a)-(e).*** Clearly, one skilled in the art would appreciate that the particular pentapeptides were intended to fall within the scope of the claimed genus of peptides and, therefore, would conclude that the recited features were not required in combination.

In addition, Applicants direct the Examiner's attention to page 32, lines 25-27 and page 34, lines 5-11 in which the specification makes clear that the invention "relates to peptides of formula V... or variants thereof wherein the peptide is ***modified by at least one of a deletion, addition or substitution of one or more amino acid residues...,***" thereby implying that the recited features are exemplary. Indeed, the specification makes clear that the recited features of formula V are not required in combination.

Applicants further direct the Examiner's attention to M.P.E.P. § 2163(II)(A)(3)(b) which recites that

[t]o comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim 'is not present in the written

description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.' *Hyatt v. Boone*, 146 F.3d 1348, 1353... (Fed. Cir. 1998).

Indeed, the claimed genus of molecules may be supported either explicitly, implicitly or inherently by the teachings of the specification. The appropriate perspective in ultimately determining support with respect to priority and written description is that of a skilled artisan upon reading the teachings of the specification. Applying such standard to the present case, Applicants submit that the claimed genus of peptides are sufficiently supported both by the explicit and implicit teachings of the present specification taken in context and, further, the teachings of priority U.S. Application No. 10/441952, as would be understood by a skilled artisan. Indeed, Applicants submit that one skilled in the art would appreciate that the teachings of the specification make clear that the recited features are exemplary and not required together in combination.

Notwithstanding the foregoing, solely in the interest of expediting prosecution and in no way acquiescing to the validity of the Examiner's rejection, Applicants have amended the claims to further clarify and specify that the claimed peptides are specifically recited variants of formula V, as supported by the specification. Accordingly, Applicants submit that the claims as amended are entitled to priority at least as early as the filing of U.S. Application No. 10/441952 on May 19, 2003.

Claim Objections

Claims 49-50, 69 and 71-73 are objected to for the following informalities:

Claims 71-73 are objected to for not ending in a period...

Claims 49-50, 69 [and] 71-73 are objected to for inconsistent nomenclature.

Claims 49 and 50 use the abbreviation pFPhe, claims 71-73 use the abbreviation PFF, and claim 71 uses the abbreviation pFF. Claims 49 use the abbreviation mClPhe, claims 71-73 use the abbreviation MCIF, and claim 71 uses the abbreviation mClF.

Claims 71-73 are objected to for improper Markush language... In the instant case the claims are missing the term 'or'/'and'.

Applicants respectfully submit that the present amendments render the foregoing rejections moot. Specifically, Applicants submit that the foregoing amendments introduce a period in claims 71-73, incorporate consistent abbreviations in claims 49, 50, 69 and 71-73 and

introduce “and” as appropriate in claims 71-73. Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing objections.

Rejection of Claims 49, 50 and 69 Under 35 U.S.C. § 112, Second Paragraph

Claims 49, 50 and 69 have been rejected under 35 U.S.C. § 112(b) second paragraph “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Specifically, the Office Action sets forth that

[t]he claims refer to a peptide of SEQ ID NO:293 which as defined on page 32 of the specification (line 22) states that X₉ is Phe. However, as currently recited in claims 49-50 [and] 69 the peptide of SEQ ID NO:293 has X₉ being an amino acid other than Phe. Further, claim 50 recites a condition in which R is substituted. If R is substituted how can the peptide consist of SEQ ID NO:293.

With respect to the Examiner’s rejection as it pertains to SEQ ID NO:293, Applicants submit that a revised sequence listing will be filed shortly, thereby rendering the foregoing rejection moot.

With respect specifically to claim 50, Applicants submit that claim 50 as amended sets forth that the peptide consists of formula V (*i.e.*, RX₆X₇X₈X₉) **or a variant thereof**, with specifically recited conditions, thereby rendering the foregoing rejection moot.

Rejection of Claims 49, 50 and 69 Under 35 U.S.C. § 112, First Paragraph

Claims 49, 50 and 69 have been rejected under 35 U.S.C. § 112(b) first paragraph “as not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Specifically, the Office Action sets forth that

In the instant case an RCE has been filed, which is not the filing of a new application (MPEP 706.07(h)), with claims that are not supported in the original disclosure.

Applicant has noted that the current application is a continuation-in-part of previous applications and note that support for the amendments to claims 49-51 can be found throughout the specification, for example at page 33 lines 22-25 and at page 35 lines 1-5 and in the claims as originally filed for example claims 67-68. However, the claims as amended (49-51 and dependent claims) recite a particular subgenus that is not supported by the original application. Page 33 lines 22-25 recite a condition for X₉, but do not recite the subgenus of the current claims. For example, page 33 lines 10 and 13 support a peptide in which R is replaced and X₆ is replaced. However, claims 49-50 support a subgenus in which R can be unchanged (*i.e.* does not agree with original disclosure of R is replaced). Claims 49-51 support a subgenus in which X₆ can be unchanged (*i.e.* does

not agree with original disclosure of X₆ is replaced). Although applicants claim support from claims 67-68 as originally filed, there were no claims 67-68 as originally filed. Hence, claims 49-55, 57-66 [and] 69-70 are not described by the originally filed specification.

Applicants respectfully disagree. In support, Applicants direct the Examiner's attention to the foregoing discussion under the section entitled "Priority" in which the Applicants detail how the present specification and priority U.S. Application No. 10/441952, the teachings of which are incorporated by reference to the present specification, provide support for the pending claims. Indeed, in view of the standard set forth in M.P.E.P. § 2163(II)(A)(3)(b), Applicants submit that the teachings of the specification, taken in context, and as discussed in detail above, provide sufficient support for the claims as pending.

In view of the foregoing discussion and the amendments set forth herein, Applicants respectfully request reconsideration and withdrawal of the pending claims as lacking written description.

Rejection of Claims 49, 50 and 69 Under 35 U.S.C. § 102(b)

Claims 49, 50 and 69 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Publication No. 2005/0260730 to Fischer *et al.* (hereinafter referred to as "Fischer") on the ground that Fischer "teach a peptide (section 0015 SEQ ID NO:4) and acetylation of peptides (section 0104) which meets the claim limitations."

Applicants respectfully traverse the foregoing rejection on the ground that Fischer fails to anticipate the claimed invention. Notwithstanding the foregoing, Applicants submit that Fischer fails to qualify as prior art under 35 U.S.C. § 102(b). Indeed, as set forth above, Applicants submit that the claimed invention is entitled to the priority date of May 19, 2003 and therefore predates the Fischer reference. Accordingly, because Fischer fails to qualify as prior art under 35 U.S.C. § 102, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

Rejection of Claims 50 and 69 Under 35 U.S.C. § 102(b)

Claims 50 and 69 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Brinker *et al.* (European Journal of Biochemistry (2000)) (hereinafter referred to as "Brinker")

on the ground that Brinker “teach a peptide... of sequence RKLLW which can be acetylated which meets the claim limitations (note that L is a conservative substitution for I).”

Applicants respectfully traverse the foregoing rejection on the ground that Brinker fails to anticipate the claimed invention. Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the validity of the Examiner’s rejections, Applicants have amended claim 50, thereby rendering the foregoing rejection moot. Applicants submit that the peptide of claim 50, as amended, is not anticipated by Brinker and, specifically, Brinker’s disclosure of the sequence RKLLW. Specifically, Brinker fails to teach the requisite limitations for residue X₈, as set forth in claim 50. Accordingly, because Brinker fails to teach each and every limitation of the claimed invention, Applicants submit that Brinker fails to undermine the novelty of the pending claims. Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

Provisional Rejection Under 35 U.S.C. § 101

Claims 71-73 have been provisionally rejected under 35 U.S.C. § 101 “as claiming the same invention as that of claims 20, 21, [and] 22 of copending Application No. 11/407,880.”

Applicants respectfully disagree. However, while in no way acquiescing to the outstanding rejection, Applicants note that prosecution of the present application and copending Application No. 11/407,880 may render such rejection moot. Accordingly, Applicants will address such rejection as appropriate upon allowance of the claims in U.S. Application No. 11/407,880 or once the pending claims in the present application are formally indicated as otherwise allowable.

**Provisional Rejection Under Judicially Created Doctrine of
Obviousness-type Double Patenting**

Claims 49, 50 and 69 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting “as being unpatentable over claims 16, 17, 18 and 23 of copending Application No. 09/726,470.”

While in no way acquiescing to the Examiner’s rejections under the judicially created doctrine of obviousness-type double patenting, Applicants note that prosecution of the present

application and copending Application No. 09/726,470 may render such rejection moot. Accordingly, once the pending claims in the present application are formally indicated as otherwise allowable, and should such submission(s) be necessary, Applicants will submit a terminal disclaimer in compliance with C.F.R. §§ 1.321(b) and (c), as appropriate, which will obviate this rejection.

Withdrawal of Claims 51-55, 57-66 and 70

Applicants acknowledge the election of Group 142 (*i.e.*, claims 49-51 drawn to a peptide of formula V/SEQ ID NO:293) and the species of SEQ ID NO:295 as set forth in the Responses to Restriction Requirement of November 9, 2005 and November 29, 2005.

In the Office Action, “[c]laims 51-55, 57-66 [and] 70 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.” Specifically, the Examiner asserts that

[i]n the instant case the elected species was not found allowable (see priority section below). Claims that read on a replacement or substitution are distinct from the elected species and held withdrawn.

Applicants submit that in view of the foregoing amendments and arguments presented herein, the instantly prosecuted species is in condition for allowance. Accordingly, Applicants respectfully request rejoinder of claims 51-54, 57-66 and 70.

SUMMARY

Applicants respectfully submit that the above-identified application is in condition for allowance. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the present filing to Deposit Account No. 12-0080 under Order No. CCI-014CP2RCE, from which the undersigned is authorized to withdraw.

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Respectfully submitted,

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